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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,717	04/13/2000	Katsuya Daimon	472552000100	7198

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/548,717	DAIMON ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-23 and 25* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) filed on July 24, 2004. The request for RCE is accepted and is established with the status of the application as follows:

a. the filling date of this RCE is established as April 13, 2000;

b. Claims 1 is amended. Claims 2, 8, 24 are cancelled. Claims 1, 3-7, 9-22, 25 are considered for examination. Claim 23 is withdrawn in view of restriction/election.

2. Applicants' response to the earlier office action filed on January 9, 2004 is reconsidered and has been entered.

New Grounds of rejections

Objections

3. Claim 8 is objected because claim 8 is canceled in the amendment filed on April 19, 2002. However, the instant amendment presents claim 8 as an active claim. Clarification and correction is required.

Claim Rejections - 35 USC § 112

4A. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, 9-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)".

Here, the new limitation of "nucleic acids being bound to the silica particulate carrier via hydrogen bonds formed between hydroxyl groups of silica of the particulate carrier surface and bases of the nucleic acids" in the claim 1 appears to represent new matter. After a careful review of the specification, it is noted that this limitation was not present, in the instant specification. Thus the limitation as recited lacks descriptive support in the specification.

Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

4B. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-7, 9-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "essentially consisting of the steps", which makes the claim indefinite and incomplete because the meets and bounds of the claim are unclear, that is, it is not clear what steps are essential to carry out the method or what steps are critical to carry out the method to achieve the extraction of nucleic acids from a material. And what steps are not necessary to carryout the method as recited.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-7, 9-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom et al. (USPN. 5,234,809).

Boom et al. teach a method of claim 1, 3, 8 and 25, for extracting nucleic acids from a material containing nucleic acids using nucleic acid-binding particulate carrier which contains silica or its derivative, comprising the steps of

(a) mixing the material containing nucleic acids with a nucleic acid-binding particulate carrier (silica coarse (SC)) having a particle size ranging 0.5and 500 um, allowing the nucleic acids to adsorb (binding) to the particulate carrier (see col. 5, line 18-40, col. 8, line 14-25, col. 2, lines 52-63);

(b) separating a composite of nucleic acids and the particulate carrier from the mixture obtained in step (a) (see col. 8, line 26-31);

(c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier (see col. 8, line 32-35).

With regard to claims 9-11, Boom et al. teach that the nucleic acids are DNA and or RNA comprising biological material including body fluids, (such as serum, urine), blood, and feces (see col. 8, line 14-19);

With regard to claims 12-14, Boom et al. teach that the extraction solution contains chaotropic substance as guanidine thiocyanate , potassium iodide, urea (see col. 5, line 18-30, col. 7, line 15-31);

With regard to claims 15-18, Boom et al. teach that the wash solution comprises first wash solution (70% alcohol) containing chaotropic substance and a second washing solution containing alcohol (see col. 8, line 28-29, col.6, line 50-52);

With regard to claims 19-22, Boom et al. teach that detecting a target nucleic acid comprises extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction, which is a nucleic acid sequence based amplification (NASBA) (see col. 4, line 45-59, col. 8, line 64-68).

However, Boom et al. did not specifically teach the particulate carrier dimensions suitable for adsorption of nucleic acids.

Yamauchi et al. teach a method of claims 1, 25, for isolating nucleic acids using silica-coated magnetic particles wherein Yamauchi et al. disclose that the method comprises (a) mixing nucleic acid containing material with a nucleic acid- binding particulate carrier (silica coated magnetic particle) with a particle diameter of ranging from 1 to 200 um and more preferably ranging from 1 to 20 um, a pore diameter ranging from 1 to 100 nm, a pore volume of 0.1 to about 2.5ml/g (see column 4, lines 6-47, column 5, lines 48-67, column 6, lines 1-14, column 13, lines 10-19);
(b) separating a composite of the nucleic acids and the particulate carrier from the mixture to remove contaminants (see column 13, lines 19-23); (c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier (see column 13, lines 23-30).

Yamauchi et al. also teach that the method comprises (i) the magnetic silica particulate carrier contains superparamagnetic metal oxide (with regard to instant claim 4) (see column 3, lines 49-60) and the metal oxide contained an amount of about 5 to about 50% by weight (with

regard to instant claim 5) (see column 4, lines 62-64); (ii) a surface area of the particulate carrier ranges from 10 to 800 m^2 /g (with regard to instant claims 6-7) (see column 6, lines 15-22); (iii) the nucleic acids comprises DNA, and /or RNA, and the nucleic acids containing biological material include body fluids (with regard to instant claims 9-10) (serum of HCV-infected persons) (see column 16, lines 15-18); (iv) the method contains extraction of nucleic acids with wash solutions containing chaotropic substance (guanidine thiocyanate) and alcohol (40% isopropanol) (with regard to instant claims 15-18)(see column 16, lines 19-55); nucleic acids bind to the silica particulate derivative via hydrogen bonds between hydroxyl groups on the particle surfaces of the carrier (silanol group, Si-OH) (with regard to instant claim 1) (see column 8, lines 52-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of extracting nucleic acids as taught by Boom et al. with the step of adding nucleic acid-binding particulate carrier dimensions as taught by Yamauchi et al. which is suitable for binding nucleic acids because Yamauchi et al. taught that the particulate carrier shape and stability with the specified dimensions provide higher dispersibility in a sample-containing solution to maintain dispersion with stirring, with less sedimentation tendency and the nucleic acid bound particulate carrier can readily be separated from the sample containing solution (see col. 5, line 48-63). Further Yamauchi et al. taught that the shape and stability of the particulate silica carrier provides higher adsorption capacity, higher adsorption speed and higher reaction efficiency in adsorption and extraction (see col. 4, line 2329). An ordinary practitioner would have been motivated to combine the method of Boom et al. with the particulate carrier dimensions as taught by Yamauchi et al in order to achieve the

expected advantage of developing a method to enhance binding of nucleic acids to the particulate carrier and to obtain higher yield of isolated of nucleic acids with better particulate dimensions, which can hold or adsorb more nucleic acids from a sample.

Response to Arguments

6. Applicants' response to the office action is fully considered and found persuasive.

7. With reference to the rejection under 35 USC 102(e), Applicants amendment and arguments are fully considered and the rejection is withdrawn herein for the claims 1-7, 9-22, and 25 in view of the amendment and arguments and new grounds of rejection.

8. With reference to the rejection under 35 USC 103(a), Applicants amendment and arguments are fully considered and the rejection is with drawn herein in view of the amendment and arguments and new grounds of rejection.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
August 5, 2004

JEFFREY FREDMAN
PRIMARY EXAMINER
8/6/04